

### REMARKS

Claims 8, 11, and 15-18 are pending in this application. Claim 8 has been amended without prejudice and without acquiescence to include the limitation of claim 21. Claims 14 and 21 have been canceled without prejudice and without acquiescence. Applicants assert no new matter has been added.

The following issues are outstanding in the office action:

- Claims 17-18 and 21 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.
- Claims 8, 11, 14-18 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 11/522, 721 in view of Farmer (US 6461607).
- Claims 8, 11, and 14-16 were rejected under 35 U.S.C. § 102(e) as being anticipated by Farmer (US 6461607).

#### 35 U.S.C. § 112

The Examiner has rejected claims 17-18 and 21 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse.

Applicants assert that the microorganism in the present application has been deposited in accordance with the Budapest Treaty and therefore has been made readily available to the public. Included in the documents submitted with the 371, specifically, on pages 17-18 of the International Publication Application, is a copy of the deposition of the microorganism. Also, included herein as an appendix is the application form submitted with the microorganism deposited with the National Collections of Industrial, Food and Marine Bacteria (NCIMB) in accordance with the Budapest Treaty. The application specifies agreement to the release of

samples (page 2, item 6) and replacement of the culture in the event of it becoming non-viable (page 1, item 2). The enclosed copies also indicate on page 3, item 1 that the deposit was made under the Budapest treaty.

In light of the above arguments and the attached appendix, Applicants respectfully request that the rejection be withdrawn.

Nonstatutory Double Patenting

The Examiner has provisionally rejected claims 8, 11, 14-18 and 21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 11/522, 721 in view of Farmer (US 6461607). Applicants respectfully traverse.

The Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated: "Once the provisional rejection has been made, there is nothing the examiner and the applicant must do until the other application issues." *In re Mott*, 190 USPQ 536, 541 (CCPA 1976) (emphasis added). MPEP §804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such provisional rejection until one of the applications issues a patent.

Thus, Applicants respectfully request that this rejection be held in abeyance until the conflicting claims are in fact patented.

35 U.S.C. § 102

The Examiner has rejected claims 8, 11, and 14-16 under 35 U.S.C. § 102(e) as being anticipated by Farmer (US 6461607). Applicants respectfully traverse.

Farmer does not disclose the specific *Lactobacillus* strain claimed in the present Application. Claim 8 has been amended to incorporate the limitations of claim 21, therefore, specifying the specific strain of *Lactobacillus acidophilus* deposited under accession number NCIMB 41117. Applicants would remind the Examiner that a claim is anticipated only if each and every element of the claim is found. *Verdegaal Bros. v. Union Oil Co. of California*,

814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) MPEP 2131. Since Farmer does not teach the strain of *Lactobacillus* deposited under NCIMB 41117 this reference does not teach all the claim limitations.

In light of the amendment to claim 8 and the argument above, Applicants respectfully request that the rejection be withdrawn.

### **CONCLUSION**

In view of the above, applicant believes the pending application is in condition for allowance.

A three month extension of time fee is being submitted with this response. If additional fees are due, please charge Deposit Account No. 06-2380, under Order No. 9276/HO-P03101US0/10415825 from which the undersigned is authorized to draw.

Dated: 08-24-07

Respectfully submitted,

By 

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Attorney for Applicant

**APPENDIX**

**Application form submitted with deposited microorganism.**

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## DEPOSIT FOR THE PURPOSES OF PATENT PROCEDURE

## APPLICATION FORM

I/We request NCIMB Ltd to accept for deposit for the purposes of patent procedure the following organism(s):

(Name of organism(s) and depositor's strain or cultivar designation, if any).

*Lactobacillus acidophilus* (ML1)

I/We understand that if after examination of the organism(s) and/or the information contained in the Accession Form(s) enclosed herewith, NCIMB Ltd shall find the organism(s) not to be of a kind which it accepts for deposit for the purposes of patent procedure, NCIMB Ltd shall refuse to accept the organism(s) and shall notify me/us forthwith of such refusal. In such cases, unless I/we request the return of the organism(s) within 28 days of such notification, NCIMB Ltd shall be entitled to destroy it.

If NCIMB Ltd agrees to accept the organism(s), I/we agree to be bound by the following terms and conditions:

1. I/We have provided all the information and indications requested by NCIMB Ltd on the Accession Form(s) established by NCIMB Ltd for that purpose and enclosed herewith.
2. I/We may replace at my/our expense, according to the relevant patent regulations, the deposited organism(s), if it (they) should deteriorate or cease to exist, so that NCIMB Ltd is no longer able to furnish samples, following receipt from NCIMB Ltd of notification of such inability to furnish samples.

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3. I/We will pay to NCIMB Ltd all fees charged for the storage of the organism(s) and the supply to me/us of samples thereof.
4. I/We will indemnify NCIMB Ltd against all claims that may be brought against NCIMB Ltd as a result of the release of samples of the organism(s), unless such claims arise of account of the negligence of NCIMB Ltd, its servants or agents.
5. I/We will not require the return of the organism(s), to me/us, for a period of 30 years after the date the organism(s) is (are) accepted for the purpose of patent procedures, or 5 years after the date of the last request for a sample thereof, whichever is the latter, during which period NCIMB Ltd shall have the right to retain the organism(s).
6. I/We will authorise NCIMB Ltd to release samples of the organism(s) only in accordance with the provisions of Rule 11 of the Budapest Treaty in any case where the deposit is intended to serve for the purposes of patent procedure for any state which has ratified the Treaty, or organisation which has made the declarations referred to in Article 9 of the Treaty. In any other case, I/we will authorise NCIMB Ltd to release such samples only:
  - (i) on my/our written authorisation; or
  - (ii) on the written authorisation of the following industrial property office(s) (specify industrial property offices):
7. I/We will abide by the above terms and conditions, which may be varied from time to time for the purpose of compliance with any Treaty or Convention to which the United Kingdom is a party.

Signature of Depositor .....

For and on behalf of Mars, Inc

Name .....

Date .....

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## DEPOSIT FOR PURPOSES OF PATENT PROCEDURE

Leave Blank

ACCESSION FORM

Date deposit received

10/10/01

Accession no.

41117

PLEASE COMPLETE PART 1, THEN PART B OR C AS APPROPRIATE

## PART A (ALL DEPOSITS)

1. Is the deposit being made under the Budapest Treaty?

☒ YES ☐ NO

2. Name of depositor and address for correspondence:

Mars, Incorporated  
6885 Elm Street  
Virginia  
22101, USA

Tel:

Telex:

Dr M.L. Baillon  
NCPN  
Hathorn-on-the-Wolds  
Leic. LE14 9RT

Fax:

3. Name and address of Patent Agent to whom official notifications and/or correspondence should also be sent:

Kristina Cornish  
Kilburn + Strode  
20 Red Lion Street  
London.

Tel: 0207 539 4200

Telex:

Fax: 0207 539 4299

4. Is unofficial telephone/telex notification of provisional accession number and deposit date required in advance of formal documentary confirmation?

☒ YES ☐ NO

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## PART B (All deposits EXCEPT plant seeds)

5. Name of the microorganism (genus and species), if known:

*Lactobacillus acidophilus*

6. Depositor's strain designation:

WAL ML1

7. Can the microorganism be preserved without significant changes in its properties by:

- (i) Freeze-drying (lyophilization) in serum/glucose broth ("mist, desiccans")?

YES/NO/NOT KNOWN

- (ii) Freezing in 10% glycerol broth?

YES/NO/NOT KNOWN

8. Can the microorganism be grown routinely on nutrient agar or in nutrient broth without significant changes in its properties? (e.g. requirement for growth on antibiotic supplemented media for plasmid maintenance).

\* Freezes well on cryobeads

YES/NO/NOT KNOWN

9. If the answer to 8 is other than YES, please specify a suitable medium including any supplements (e.g. antibiotics) for growing and testing the viability of the microorganism. For naked plasmids, please provide transformation protocols. (Use a separate sheet if necessary)

de Man, Rogosa  
and Sharpe  
(MRS) agar  
(oxid).

10. Please specify:

- (i) suitable incubation temperature;

37-38 °C

- (ii) suitable incubation atmosphere;

Anaerobic

- (iii) any special incubation conditions.

11. If the deposit is a mixed culture, please describe the components and at least one of the methods for checking the presence of each. (Use a separate sheet if necessary)

N/A

12. Is the deposit known to be, or likely to be hazardous to the health of:

- (i) man?

YES/NO

- (ii) animals (please specify)?

YES/NO

- (iii) plants (please specify)?

YES/NO

- (iv) the environment (please specify)?

YES/NO

If the answer to any of (i)-(iv) above is YES, please give details, including hazard rating and required containment level.



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PLEASE SIGN AND DATE THIS FORM AT 25 BELOW

## PART C (Plant seeds ONLY)

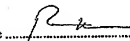
13. Name(s) of the parent plant(s) (genus, species, cultivar or variety), if known:
14. Depositor's cultivar designation:
15. Number of seeds supplied:
16. Date and method of harvest:
17. Conditions under which seeds have been kept since harvesting:
18. Can the seeds be dried to a low (c. 4-6%) moisture content and stored at temperatures lower than -20°C (i.e. orthodox seeds)? YES/NO/NOT KNOWN
19. Have the seeds already been pre-dried for immediate low temperature storage? YES/NO/NOT KNOWN
20. Please specify suitable conditions for testing germination, including any protocols necessary for overcoming dormancy. (Use a separate sheet if necessary)
21. Please specify:
- (i) expected % germination rate:
- (ii) average time required for germination:
22. Have the seeds been derived from any activity which:
- (i) has involved genetic manipulation? YES/NO
- (ii) has involved genetic manipulation which has resulted, or is likely to result in the production of a plant pest? YES/NO
- (iii) has involved genetic manipulation of a plant pest? YES/NO
- If the answer to any of (i)-(iii) above is YES, please specify the nature and source of the foreign genetic material contained in the seeds.

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23. Please give any other information that may be useful for the handling and storing of the deposit.
24. For deposits outwith the UK a phytosanitary certificate may be required for importing seeds. Please contact NCIMB for further information.

PLEASE SIGN AND DATE THIS FORM AT 25 BELOW

25. Depositor's signature



Date 2 October 2001

For and on behalf of Mars, Inc

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**IMPORTANT****THIS SECTION MUST BE COMPLETED FOR ALL ORGANISMS**

1. Has this organism been derived by genetic manipulation?  
YES NO
2. (i) If the answer to 1 above is NO, please sign the declaration below.  
(ii) If the answer to 1 above is YES, please complete the GMO supplementary Accession Form, before signing the declaration at the end of the form.

We regret that the deposit cannot be accepted and processed until these forms have been completed and returned. We will be pleased to supply further details on this process to assist you.

Alternatively, advice and information can be obtained from:

Health & Safety Executive  
Health Policy Division B2  
2 Southwark Bridge  
LONDON  
SE2 9HS

Telephone No: 0171 727 6337

**WARNING:** If you are working with a genetically manipulated organism in a UK laboratory and have not done a risk assessment and have not been exempted in writing by the Health & Safety Executive from carrying out such a risk assessment, you may be in breach of the Genetically Modified Organisms (Contained Use) Regulations, 1992.

**DECLARATION**

We hereby declare that to the best of our knowledge, the information given above is true and correct.

Signed 

Signed .....

Depositor

Biological Safety Officer

Date 28.9.01

Date .....

**BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE**

Mars Incorporated  
6885 Elm Street  
Virginia 22101  
USA

**INTERNATIONAL FORM**

**VIABILITY STATEMENT**  
issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY STATEMENT  
IS ISSUED

<b>I. DEPOSITOR</b>	<b>II. IDENTIFICATION OF THE MICROORGANISM</b>
Name: AS ABOVE Address:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: NCIMB 41117  Date of the deposit or of the transfer <sup>1</sup> :  10 October 2001
<b>III. VIABILITY STATEMENT</b>	
The viability of the microorganism identified under II above was tested on 12 October 2001 <sup>2</sup> . On that date, the said microorganism was:  <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <input checked="checked" type="checkbox"/> <sup>3</sup>  <input type="checkbox"/> </div> <div>             viable              no longer viable           </div> </div>	

<sup>1</sup> Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

<sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

<sup>3</sup> Mark with a cross the applicable box.

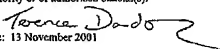
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED<sup>4</sup>

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: NCIMB Ltd.,

Address: 23 St Machar Drive,  
Aberdeen,  
A24 3RY,  
Scotland.Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorised official(s):

Date: 13 November 2001

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.